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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,925	05/30/2001	Richard J. Feldmann	3124-Z	5146

7590 10/08/2003

Law Office of Jim Zegeer
801 North Pitt Street, #108
Alexandria, VA 22314

EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,925	FELDMANN, RICHARD J.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The substitute specification filed on 07 August 2003 has been entered.
2. The objection to the specification regarding SEQ ID NOS in the Office action mailed 08 January 2003 is withdrawn in view of the substitute specification filed on 07 August 2003.
3. The objection to the specification regarding a hyperlink in the Office action mailed 08 January 2003 is withdrawn in view of the substitute specification filed on 07 August 2003.
4. The objection to the specification regarding the brief description of the drawings and the index in the Office action mailed 08 January 2003 is withdrawn in view of the substitute specification filed on 07 August 2003.
5. The disclosure is objected to because of the following informalities:

On page 30, line 3, the reference listed with the bibliography number “[1]” does not correspond to the reference listed in the bibliography.

Appropriate correction is required.

Claim Objections

6. The objection to claim 20 in the Office action mailed 08 January 2003 is withdrawn in view of the substitute specification filed 07 August 2003.
7. Claim 36 is objected to because of the following informalities: In claim 36, line 2, the term “do” should be amended to recite “does.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 20-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must identify and use a connectron to predict regulation of gene expression. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The description provides guidance to identify connectron symmetries in genomic sequences. The description does not provide detailed guidance to use identified connectron symmetries to predict an effect on gene expression.

c) The description provides working examples of identification of connectron symmetries in genomic sequences. The description does not provide working examples of using identified connectron symmetries to predict effects on gene expression.

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d) The nature of the invention, gene expression control, is complex.

e) The prior art does not show connectrons. Mattick (published in 2001, one year after the effective instant filing date) reviews effects of RNA molecules on gene regulation. Mattick does not show connectrons as defined in the instant specification.

f) The skill of those in the art of gene expression is high.

g) The predictability of the relationship of connectron symmetries and gene expression is unknown in the prior art.

h) The claims are broad in that they are drawn to identification of connectron symmetries whose relationship to gene expression is not established.

The skilled practitioner would first turn to the instant description for guidance in using the claimed invention. However, the description lacks clear evidence that connectron symmetries are related to gene expression. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not discuss connectron symmetries. Finally, said practitioner would turn to trial and error experimentation to determine a relationship between connectron symmetries and gene expression. Such amounts to undue experimentation.

10. Applicant's arguments filed 09 June 2003 have been fully considered but they are not persuasive. The applicants state in their arguments, and declarants James Oberthaler and Richard Pastor that one of skill in the art is enabled to determine sequences that have the claimed relationship to genomic sequences. It is agreed that sequences that have the claimed relationship to genomic sequences could be determined. However the applicants have failed to provide evidence that the claimed methods could be used to predict regulation of gene expression. The specification concedes on page 29 in paragraph 113 that "The physical existence and lifetimes of

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the connectrons must be proved by molecular biological experimentation.” Although some of the exemplified RNA molecules may exist as transcripts in cells, their role in regulation of gene expression has not been observed. In the absence of a showing by the applicants in the specification or subsequent declarations, or by the prior art, that the claimed methods can be used to predict gene expression the rejection is maintained.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. The rejections under 35 U.S.C. 112, second paragraph in the Office action mailed 08 January 2003 that are not reiterated below are withdrawn.

13. Claims 22-25 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite because it is not clear whether the claim is drawn to a method of modifying gene expression or a method of computer mediated identification of connectron organization. The rejection would be overcome by amending claim 25 to delete the preamble reference to modification of a genome.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step of modifying expression of different gene collections in a genome. The rejection would be overcome by amending claim 22 to be drawn to a computer mediated method of detecting changes in expression of different gene collections in a genome.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step of detecting where and when genes are integrated. The rejection would be overcome by amending claim 23 to be drawn to a computer mediated method of detecting links between newly introduced genes and preexisting connectrons.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step of detection of the effect of gene collections on transcription because it is not clear that the recited step of detecting the effect of connectrons on transcription is equivalent to detection of expression effects in vivo. The rejection would be overcome by amending claim 24 to be drawn to a computer mediated method of detecting connectrons.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step of changing the expression of different gene collections. The rejection would be overcome by amending claim 25 to be drawn to a method of computer mediated identification of connectron organization.

Claim 28 recites the limitation "the tetradic relationship." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 28 to recite "where the DNA sequence and the RNA molecule can form a tetradic relationship such that."

For the purpose of examination, the claims have been assumed to incorporate the

suggested amendments.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

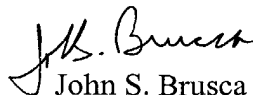
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.


John S. Brusca
Primary Examiner
Art Unit 1631

jsb